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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|----------------------|------------------------|------------------|
| 10/708,724 | 03/19/2004 | David R. Duncan | MONS:126US | 2723 |
| 73905 7590 08/03/2009 SONNENSCHEIN NATH & ROSENTHAL LLP P.O. BOX 061080 | | | EXAMINER | |
| | | | ROBINSON, KEITH O NEAL | |
| | SOUTH WACKER DRIVE STATION, WILLIS TOWER CHICAGO, IL 60606 | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |
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| | | | 08/03/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|--|-----------------------|--|--|--|--|
| Office Action Comments | 10/708,724 | DUNCAN ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | KEITH O. ROBINSON | 1638 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 23 Ap | oril 2009 | | | | | |
| · <u> </u> | <u> </u> | | | | | |
| | <u> </u> | | | | | |
| ,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-17</u> is/are pending in the application. | | | | | | |
| , | 4a) Of the above claim(s) <u>9-15</u> is/are withdrawn from consideration. | | | | | |
| | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>1-8,16 and 17</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)⊠ The drawing(s) filed on 19 March 2004 is/are: a | 10)⊠ The drawing(s) filed on <u>19 March 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the o | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) X Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da 5) Notice of Informal P | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | ателт Аррітсатіоп | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

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DETAILED ACTION

1. In the interview conducted April 16, 2009, it was agreed that the Examiner would re-open prosecution of the instant application (see 'Examiner Interview Summary' filed April 28, 2009). Thus, the finality of the rejection of the last Office action, mailed February 2, 2009, has been withdrawn.

2. Claims 1-8, 16 and 17, filed October 7, 2008, are under examination.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "an effective amount of an auxin and an effective amount of a cytokinin". It is unclear what are the metes and bounds regarding an effective amount of an auxin and an effective amount of a cytokinin.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 7. Claims 1-8, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reichert et al (U.S. Patent No. 6,140,555, October 31, 2000), in view of Saxena et al (U.S. Patent No. 5,477,000, December 19, 1995), in view of O'Connor-Sanchez et al (Plant Cell Reports 21: 302-312, 2002).

Claims 1-8 read on a method of obtaining transformable callus tissue comprising

(a) germinating a mature corn seed in tissue culture media containing an effective

amount of an auxin and an effective amount of a cytokinin to produce a growing

seedling containing a nodal section; (b) isolating said nodal section from said seedling;

and (c) culturing said nodal section to produce embryogenic callus suitable for

transformation.

Reichert et al teach methods for obtaining transformable callus tissue (see, for example, column 2, line 59 to column 3, line 5 where it teaches that immature zygotic

embryos can be used as explants for callus cultures and Table 1 where it lists several references that teach methods for obtaining transformable callus tissue)

With regard to claim 1, step (a), O'Connor-Sanchez et al teach germinating mature corn seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section. See, for example, page 303, 1st column, 'Materials and methods' where it teaches mature corn seeds used in six culture media wherein said media was supplemented with cytokinin (BA) and auxin (2,4-D).

With regard to claim 1, step (b), Reichert et al teach isolating the nodal section from the seedling. See column 3, lines 62-63 where it teaches "[s]eedling nodal tissues from inbred [corn] were excised". It would have been obvious to one of ordinary skill in the art that in isolating nodal section one would have to excise tissue.

With regard to claim 1, step (c), Reichert et al teach culturing nodal section on induction media. See, for example column 10, line 65 to column 11, line 15, where it teaches "[n]odal section explants are placed on corn shoot induction medium".

See column 17, line 46 to column 18, line 14 where Reichert et al teach nodal sections derived from mature seeds, transforming the callus with a nucleic acid sequence and selecting transformed callus cells.

With regard to claim 2, Saxena et al teach "growth regulators may be selected from several known growth regulators. See column 7, lines 14-15. It would have been obvious to one of ordinary skill in the art that any auxin and any cytokinin or a combination thereof could be used as growth regulators a in the tissue culture media.

Saxena et al teach growth regulators used in the medium may be one or more components selected from any one group or components mixed and selected from two or more of the above listed groups [wherein the above listed groups lists examples of cytokinins and auxins]. See column 7, lines 7-29. BAP and picloram were known growth regulators. See, for example, page 7, paragraph 0027 in the specification where it is taught that picloram is a commonly used auxin and BAP is a commonly used cytokinin.

With regard to claim 3, Reichert et al teach the picloram concentration of 3.0 mg/L, which is between about 0.5 mg/L and about 20 mg/L. See, for example, column 3, line 67 to column 4, line 1.

With regard to claim 4, Reichert et al teach a BAP concentration of 2.0 mg/L, which is between about 0.1 mg/L and 10 mg/L. See column 5, line 55.

With regard to claim 5, Saxena et al teach a solid culture medium. See column 7, lines 7-13. One of ordinary skill in the art would appreciate that media containing gelrite or agar would be solid.

With regard to claims 6 and 7, Reichert et al teach nodal section obtained from seedling 7 days after germination. See column 5, lines 52-56 where it teaches explant were excised after 7 days.

With regard to claim 8, see column 17, line 46 to column 18, line 14 where Reichert et al teach transforming the callus with a nucleic acid sequence and column 21, line 52 to column 22, line 6 where Reichert et al teach regenerating a transformed plant.

Claim 16 reads on a method of obtaining transformable callus tissue from a corn plant comprising: (a) priming a mature corn seed; (b) germinating a mature corn seed in

tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section capable of producing callus; (c) isolating the nodal section from the seedling; (d) culturing the nodal section on callus induction media to produce embryogenic callus.

With regard to claim 16, step (a), see, for example, column 8, lines 11-16, where Saxena et al teach the surface sterilization of seeds. One of ordinary skill in the art would appreciate that such a step could be interpreted as priming a seed.

With regard to claim 16, step (b), O'Connor-Sanchez et al teach germinating mature corn seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section. See, for example, page 303, 1st column, 'Materials and methods' where it teaches mature corn seeds used in six culture media wherein said media was supplemented with cytokinin (BA) and auxin (2,4-D).

With regard to claim 16, step (c), Reichert et al teach isolating the nodal section from the seedling. See column 3, lines 62-63 where it teaches "[s]eedling nodal tissues from inbred [corn] were excised". It would have been obvious to one of ordinary skill in the art that in isolating nodal section one would have to excise tissue.

With regard to claim 16, step (d), Reichert et al teach culturing nodal section on induction media. See, for example column 10, line 65 to column 11, line 15, where it teaches "[n]odal section explants are placed on corn shoot induction medium".

See column 17, line 46 to column 18, line 14 where Reichert et al teach nodal sections derived from mature seeds, transforming the callus with a nucleic acid sequence and selecting transformed callus cells.

Claim 17 reads on a method of transforming a corn plant comprising: (a) priming a mature corn seed; (b) germinating the mature seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section capable of producing callus; (c) isolating the nodal section from the seedling; (d) culturing the nodal section on callus induction media to form an embryogenic callus culture; (e) transforming the embryogenic callus culture with a nucleic acid sequence conferring a selected genetic trait to the transformed callus; (f) selecting transformed callus cells; and (g) regenerating a transformed plant from the transformed callus to obtain a plant containing the nucleic acid sequence.

With regard to claim 17, step (a), see, for example, column 8, lines 11-16, where Saxena et al teach the surface sterilization of seeds. One of ordinary skill in the art would appreciate that such a step could be interpreted as priming a seed.

With regard to claim 17, step (b), O'Connor-Sanchez et al teach germinating mature corn seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section. See, for example, page 303, 1st column, 'Materials and methods' where it teaches mature corn seeds used in six culture media wherein said media was supplemented with cytokinin (BA) and auxin (2,4-D).

Also Saxena et al teach germination of mature seed in tissue culture media containing an effective amount of auxin and an effective amount of cytokinin (see, for example, the 'Abstract' where it teaches, "viable regenerants can be produced by culturing an intact plant seed...in the presence of cytokinin and/or auxin growth factors". Also see, for example, column 7, lines 30-35, where it teaches, "growth regulators used in the medium may be one or more components selected from any one group or components mixed and selected from two or more of the above listed groups [wherein the above listed groups list examples of cytokinins and auxins (see column 7, lines 7-29)]). Finally, see, for example, column 7, lines 65-66 where it teaches, "[t]he use...of an auxin and TDZ [a cytokinin] are effective as well.").

With regard to claim 17, step (c), Reichert et al teach isolating the nodal section from the seedling. See column 3, lines 62-63 where it teaches "[s]eedling nodal tissues from inbred [corn] were excised". It would have been obvious to one of ordinary skill in the art that in isolating nodal section one would have to excise tissue.

With regard to claim 17, step (d), Reichert et al teach culturing nodal section on induction media. See, for example column 10, line 65 to column 11, line 15, where it teaches "[n]odal section explants are placed on corn shoot induction medium".

See column 17, line 46 to column 18, line 14 where Reichert et al teach nodal sections derived from mature seeds, transforming the callus with a nucleic acid sequence and selecting transformed callus cells.

With regard to claim 17, step (e), O'Connor-Sanchez et al teach transforming embryogenic callus culture with a nucleic acid sequence. See, for example, page 303,

2nd column, last paragraph where it teaches "[w]ell-developed calli cultured in dark were screened...to select cell clumps which contained both organogenic and embryogenic-like structures for bombardment".

With regard to claim 17, step (f), O'Connor-Sanchez et al teach selecting transformed callus cells. See, for example, page 304, 1st column, last paragraph where it teaches that organogenic/embryogenic calluses were selected twenty-four hours after bombardment.

With regard to claim 17, step (g), O'Connor-Sanchez et al teach regenerating a transformed plant from transformed callus to obtain a plant containing the nucleic acid sequence. See, for example, page 307, 1st column, 2nd paragraph where it teaches that green PPT-resistant calluses were transferred to plant regeneration conditions and it was observed that almost every one was able to regenerate at least one full plant.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the above teachings produce the claimed method because Reichert et al teach that "mature seeds would...aid transformation efforts due to the abundance of mature seeds year-round and the ability to store them until needed". See column 38, lines 58-62.

In addition, O'Connor-Sanchez et al teach germinating mature corn seed in tissue culture media containing an auxin and a cytokinin, as discussed above.

One of ordinary skill in the art would have been motivated to combine these teachings because Saxena et al teach "seed can be placed in the culture medium for purposes of regeneration which can translate into considerable savings in time, labour

and overall cost of production...[t]his feature, in combination with the significant outcrop of 10 to 20 fold greater number of regenerants, provides a significant increase in processing efficiency to prepare plants from a single seed". See column 6, lines 16-22.

In addition, one of ordinary skill in the art would have had a reasonable expectation of success based on the success of Saxena et al in regenerating plants using mature seed in tissue culture media.

Conclusion

8. No claims are allowed.

Contact Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Keith O. Robinson /David H Kruse/ Primary Examiner, Art Unit 1638